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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/721,582 | 11/25/2003 | Joseph F. Obermiller | PA-5213-CIP-CON | 5774 |
| 7590 | 10/20/2006 | | EXAMINER | |
| Charles W. Agnew Registered Patent Agent P.O. Box 2269 Bloomington, IN 47402-2269 | | | | BLANCO, JAVIER G |
| | | ART UNIT | PAPER NUMBER | 3738 |

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/721,582 | OBERMILLER, JOSEPH F. |
| | Examiner Javier G. Blanco | Art Unit 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 August 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3, 7, 11 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 11 and 14-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 7 and 18-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1 and 7 in the reply filed on December 6, 2005 is acknowledged.
2. Applicant's cancellation of claims 4-6, 8-10, 12, and 13 in the reply filed on December 6, 2005 is acknowledged.
3. Applicant's addition of claims 14-25 in the reply filed on December 6, 2005 is acknowledged.

Election/Restrictions

4. Applicant's election of INVENTION I: Claims 1, 7, and 18-25 in the reply filed on August 8, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
5. Claims 14-17 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 8, 2006. Claims 2, 3, and 11 were previously withdrawn from further consideration.

Claim Objections

6. Claim 18 is objected to because of the following informality: please substitute “overhand portion thereof” (see line 9) with --overhang portion of said flexible biomaterial--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, recently added limitation “the wall-engaging outer edge” (see line 9) lacks antecedent basis. Claims 22-25 depend on claim 1.

b. Regarding claim 18, the limitation “the vessel” (see line 5) lacks antecedent basis. Claims 19 and 20 depend on claim 18.

c. Regarding claim 21, it depends on “claim x” (see line 1).

d. Regarding claim 22, the limitation “the fixation” (see line 1) lacks antecedent basis.

e. Regarding claim 23, the limitation “the fixation” (see line 1) lacks antecedent basis.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 7, and 18-24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by DiMatteo et al. (US 6,440,164 B1).

Referring to Figures 1-4 and 14-16, DiMatteo et al. disclose an expandable implantable vascular valve comprising: (i) a support frame (trellis 24 includes scaffold 30 and leaf frames 62); (ii) one or more leaflets (e.g., valve leaf cover 80; additionally, there is a first liner 82 comprising a webbing 84) comprised of a biomaterial (see list of materials disclosed in columns 10 and 11) attached to the support frame and *configured to function* (emphasis added to functional language) as a valve; and (iii) wherein the biomaterial is wrapped around the support frame and affixed to itself by heat setting, adhesive welding, application of uniform force (= pressure), and other bonding techniques (see column 11, lines 27-32), thereby securing the one or more leaflets to the support frame (see entire document). First liner 82 could comprise at least one flap 86, or extent 80a of liner 82, that folds over the support frame and is subsequently laminated to itself, and including the entire extent of trellis 24 as shown in Figures 1 and 3 (see column 11, lines 15-20; column 12, lines 48-55). The “overhang portion” or “skirt portion” is broadly interpreted as the portion that will “overhang” before attaching/laminating to itself. Another example of an outer edge is shown in Figures 1 and 3, wherein the line denoted by character 22 shows a portion of said leaflets in contact with the vessel wall. First liner 82 could be laminated with second liner

88, therefore encasing all of trellis 24 or just scaffold 30 (see column 11, lines 21-27 and lines 32-35).

Response to Arguments

11. Applicant's arguments filed August 31, 2005 have been fully considered but they are not persuasive.

a. Regarding claim 1, the Applicant argues that DiMatteo et al. (US 6,440,164 B1) do not teach or suggest "the wall-engaging outer edge of each of the one or more leaflets comprises a folded edge". As indicated above, said limitation lacks antecedent basis. Also, said structural limitation (i.e., "the wall-engaging outer edge") can't be determined/distinguished from the claim language. DiMatteo et al. does teach and/or suggest a first liner 82 as comprising at least one flap 86, or extent 80a of liner 82, that folds over the support frame and is subsequently laminated to itself, and including the entire extent of trellis 24 as shown in Figures 1 and 3 (see column 11, lines 15-20; column 12, lines 48-55). When the valve is in the open position, an outer edge (e.g., the tip of the leaflets) of said leaflets will engage the vessel wall. Another example of an outer edge is shown in Figures 1 and 3, wherein the line denoted by character 22 shows a portion of said leaflets in contact with the vessel wall.

b. Regarding claim 7, the Applicant argues that DiMatteo et al. (US 6,440,164 B1) do not teach or suggest "the wall-engaging outer edge of each of the one or more leaflets comprises a folded edge". DiMatteo et al. does teach and/or suggest a first liner 82 as comprising at least one flap 86, or extent 80a of liner 82, that folds over the support frame and is subsequently laminated to itself, and including the entire extent of trellis 24 as shown in Figures 1 and 3 (see column 11,

lines 15-20; column 12, lines 48-55). When the valve is in the open position, an outer edge (e.g., the tip of the leaflets) of said leaflets will engage the vessel wall. Another example of an outer edge is shown in Figures 1 and 3, wherein the line denoted by character 22 shows a portion of said leaflets in contact with the vessel wall.

12. Claims 1, 7, and 18-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Duran (US 5,489,297).

Referring to Figures 16 and 17, Duran discloses a valve comprising:

- (i) A frame (stent 110) having two or more sides (a strut/leg may have an anterior side, a posterior side, and two lateral sides), the frame formed into two or more legs (each one of the three commissure supports 146 comprises at least two legs) and comprising a bioabsorbable material (e.g., polyglycolic acid, polylactic acid, polyethylenes, polyhydroxybutyrate, collagen, soluble sugars, etc; see column 11, lines 45-67);
- (ii) A covering (membrane 112) attached to at least two sides (e.g., wrapped around the strut/leg) of a first leg, a second leg, and a third leg *to form* (emphasis added to functional language) the body of a first leaflet, a second leaflet, and a third leaflet, the covering comprising a material with remodeling properties (e.g., pericardium, pleura, peritoneum, fascia lata, or other biological membrane sources; see column 12); the “overhang portion” or “skirt portion” is broadly interpreted as the portion that will “overhang” before attaching/laminating to itself.;
- (iii) Each leaflet having an inner body edge and an outer body edge (see Figures);
- (iv) Wherein each of the inner body edges comprises a flexible free edge (e.g., free edges 117) that defines a portion of the valve orifice; and

(v) Wherein the frame is flexible, and is *moveable* (capable of being moved) between a deployed configuration and a compressed delivery configuration.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo et al. (US 6,440,164 B1).

DiMatteo et al. disclose the invention as claimed (see 102(e) rejection) except for disclosing the specific bioabsorbable/remodelable material disclosed in claim 25. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the specific bioabsorbable materials disclosed in claim 25 with the valve of DiMatteo et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. This application contains claims drawn to an invention nonelected with traverse in the paper filed January 31, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

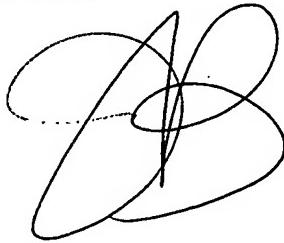
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular

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communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

October 15, 2006



David H. Willse
Primary Examiner